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REMARKS

In the final first Office Action dated December 5, 2001, it is indicated that claims 22-27, 41, 42, 46-48, and 50-58 are pending. Claims 22 and 57 have been amended and claims 59-75 have been added. Applicants contend the instant amendment places the claims in form for allowance, does not raise new issues, does not add new matter, and reduces the issues for appeal.

The pending claims are rejected under 35 U.S.C. §102(b) as being anticipated by Oshlack et al., (U.S. Pat. No. 5,639,476) and under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al., (U.S. Pat. No. 5,639,476). There are no other rejections in the application.

With respect to the rejection under 35 U.S.C. §102(b) the Examiner states,

"Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds or granules that can be coated with a coating composition comprising water-insoluble hydrophobic polymer (column 5, lines 56 - 67; and column 7, lines 35 through column 8, lines 1 - 19), water-soluble hydrophilic polymers (column 10, lines 45 - 60), modified starch (column 11, lines 12 - 41), and plasticizer (column 12, lines 29 through column 14, lines 1 - 40)."

As further stated by the Examiner, "applicant's generic claim language does not exclude the use of other components such as hydrophobic acrylic polymer".

Claims 22 and 57 have been amended to exclude the required insoluble polymer of Oshlack which, as previously discussed, is directed to a controlled release formulation. The controlled release is accomplished with an aqueous dispersion of a hydrophobic acrylic polymer, polymers that permit some release, and optional pore formers which enhance release. The pore formers identified by Oshlack include Applicants' modified starch and secondary polymers in claims 22 and 57. Claim 22 has been amended to recited that the coating does not have "a water insoluble polymer" - a necessary ingredient in Oshlack to provide timed, or slow release. Claim 57 has been amended to state that the coating "is not a delayed release coating". Support for this amendment may be found at least in the background of the application discussing prior art delayed release coatings (p1, line 28) and non-aqueous vehicles (p2, lines 5-15); and, on pages 3-4 discussing the insolubility of starch and cellulose as opposed to solubl modified starch and cellulose. In addition to the amendments to claims 22 and

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57, Applicants have submitted new claims 59-75 which do not use the word "comprising".

Applicants' contend that all of the claims distinguish over Oshlack since all embodiments of Oshlack require a water insoluble polymer, and in certain preferred embodiments the acrylic polymer includes one or more polymerizable permeability-enhancing compounds, and optionally, the diffusion rate may be further influenced by pore formers. Clearly there is no teaching in Oshlack et al. directed to a coating having modified starch, modified cellulose, and a plasticizer wherein the coating does not include a water insoluble polymer (claim 22) or is not a delayed release coating (claim 57). Such a coating would consist only of Oshlack et al.'s optional pore formers and a plasticizer.

With respect to the rejection under 35 U.S.C. §103(a) the Examiner states,

"Oshlack is relied upon for the reasons stated above. Regarding to claim 42, Oshlack is silent as to the disclosing of enzyme. However, Oshlack teaches a cleansing agent including deodorant, surfactant, germicide, and sanitizer. Hence it would have been *prima facie* obvious for one of ordinary skill in this art to, by routine experimentation determine suitable cleansing agent including enzyme. The reason for this modification is to obtain a stable coated composition that is useful in the pharmaceutical and cosmetic arts."

The Examiner further again states that "applicant's generic claim language does not exclude the use of other components such as hydrophobic acrylic polymer". It is believed that the amendments discussed above obviate this rejection.

Applicants submit the cited reference neither discloses or provides any motivation to make the claimed coating. It is impermissible within the framework of section 103 to pick and choose from any reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. Beyond looking at the cited prior art to determine if it suggests doing what the inventor has done, one must also consider if the cited art provides the required expectation of success. (In re Dow Chemical 473 USPQ2d 1529 (Fed. Cir 1988)). Both the suggestion and the expectation of success must be founded in the cited prior art and not in Applicants' disclosure. Applicants assert the Oshlack et al. reference is deficient on both accounts, and that a *prima facie* case of obvious has not been made.

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Applicants respectfully request that the rejections over Oshlack et al. be withdrawn. Pending claims 22 - 27, 41, 42, 45 - 48, 50 - 58, and added claims 59-75 are in form for allowance, and allowance of the application is kindly solicited.

Respectfully submitted,

Date:

2/1/02



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MARKED-UP VERSION SHOWING CHANGES MADE

22. (amended) A coating comprising,

- (iii) a modified starch wherein the modification includes ethylation, acetylation, methylation, hydroxypropyl substitution, hydroxyethyl substitution, carboxymethyl substitution or hydroxypropyl methyl substitution;
- (iv) a plasticizer; and
- (v) a modified cellulose as a secondary polymer, wherein the coating does not contain a water insoluble polymer.

57. (Twice amended) A coating comprising, (i) a modified starch wherein the modification includes ethylation, acetylation, methylation, hydroxypropyl substitution, hydroxyethyl substitution, carboxymethyl substitution or hydroxypropyl methyl substitution; (ii) a plasticizer; and (iii) a modified cellulose as a secondary polymer, wherein [the modified starch and the secondary polymer are provided in equal parts] the coating is not a delayed release coating.